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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

ALI, SHUMAYA B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|-------------------------------|---------------------------------|--|
| Office Action Summary | Application No. 10/727,006 | Applicant(s) CASTILLO ET AL. | |
| | Examiner Shumaya B. Ali | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-20 is/are rejected.
- 7) ☒ Claim(s) 14 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112 second paragraph for being indefinite. As to claim 16, the claim is indefinite in that the metes and bounds cannot be determined since the claim directly or indirectly depends from claim 12 which does not further limit the claim limitations "elongated arm member is fabricated from metal" disclosed in claim 16.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5-8,10-12, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bledsoe US Patent 4,463,751

3. **As to claim 1, Bledsoe discloses** a hinge system for stabilizing the human knee which stimulate the movement of the human knee and which can be utilized to restrict the range of motion of the knee to any desired range (see col.1 lines 5-9) having: a flexion-extension regulating device (see fig.5 reference objects 42 and 44) having an upper member (see fig.5 reference object 42) and a lower member (see fig.5 reference object 44) attached to each other in a manner defining a gap (as depicted in fig.5, 2 members

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inherently defines a gap when the strut 12 is disposed between the member), the there between for accommodating the end portion of the upper strut (see fig.4 reference object 12 with end portion located near reference objects 34 and 36); an elongated main slot (see fig.5 reference objects 60) formed through the upper and lower members and providing a fixed boundary for prescribing a range of motion (see col.4 lines 1-14, 51-54); and a motion limiting member (see fig.5 reference object 68) connectable (see fig.5, connectable via reference object 46) to the end portion of the lower strut (see fig.4 with end portion located near reference objects 40 and 38), the motion limiting member having a motion limiter (see fig.5 reference objects 70 and 72) disposed within the main slot which is caused to move there along (see col.4 lines 18-27) when the upper and lower struts pivot about the knee joint wherein confinement of the motion limiter within the fixed boundary ensures that the knee joint flexes and extends within the prescribed range of motion (see col.4 lines 18-31, col.14 lines 39-45)

4. **As to claim 2, Bledsoe discloses** the hinge system of claim 1 wherein the knee brace is a post-surgical knee brace (see col.1 lines 13-18).
5. **As to claim 3, Bledsoe discloses** the hinge system of claim 1 wherein the regulating device and the motion limiting member are each fabricated from metal (see col.4 lines 46-47).
6. **As to claim 5, Bledsoe discloses** the hinge system of claim 1 wherein the upper member comprises an upper body having a generally arcuate configuration (see labeled fig.5).
7. **As to claim 6, Bledsoe discloses** the hinge system of claim 1 wherein the lower member comprises a lower body having a configuration sized and configured to substantially correspond with the end portion of the upper strut (see labeled fig.5)
8. **As to claim 7, Bledsoe discloses** the hinge system of claim 1 wherein the elongated main slot is curved (arcuate) (see col.3 lines 42-45).

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9. **As to claim 8, Bledsoe discloses** the hinge system of claim 1 wherein the upper member comprises an elongated upper slot (see fig.5 reference object 60 formed within 42) and the lower member comprises a elongated lower slot (see fig.5 reference object 60 formed within 44), the upper and lower slots being substantially aligned with each other to form the elongated main slot (a main slot will inherently be defined when the 2 members are aligned according to the assembly lines of figure 5).

10. **As to claim 10, Bledsoe discloses** the hinge system of claim 1 wherein the motion limiting member has a motion limiting body (see labeled fig.5) with a first motion limiting surface the motion limiter extending outwardly in a generally perpendicular relationship with respect to the first motion limiting surface (motion limiter 70 and 72 are perpendicularly disposed in the motion limiting member and extends from the second motion limiting surface to the first motion limiting surface and further extended to be engaged with in the slots 58 and 60 as depicted in fig.5 following the proper assembly lines),

11. **As to claim 11, Bledsoe discloses** the hinge system of claim 10 wherein the lower member has a lower body with a second lower surface (see labeled fig.5), the first motion limiting surface being connected to the second lower surface (see fig.5 connected via reference objects 70,72, and 46) in a manner as to align the motion limiter within the elongated main slot.

12. **As to claim 12, Bledsoe discloses** the hinge system of claim 10 wherein the motion limiter is a flange (dictionary definition of a flange is a protruding rim, edge, rib, or collar, as on a wheel or a pipe shaft, used to strengthen an object, hold it in place, or attach it to another object. Pin 72 is protruding edge engaged in slots 60 as depicted in fig.2 is inherently capable of holding the reference objects 42 and 44 in place. Therefore, the pin 72 is considered a flange portion of the motion limiting member 66, see fig.5) fabricated from metal (see col.4 lines 46-48).

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13. **As to claim 17, Bledsoe discloses** a knee brace comprising an upper pair of struts (see fig.1 reference object 12 on the lateral and medial sides of the knee) and a lower pair of struts (see fig.1 reference object 14 on the lateral and medial sides of the knee), the upper pair and the lower pair being placeable in an inverted relative orientation above and below the knee joint (see fig.1 reference objects 12 and 14 seems to be disposed in an inverted orientation above and below a hinge 10), with end portions of the upper pair (see fig.2 reference object 12 with end portion near reference objects 34 and 36) and the lower pair being disposed laterally on opposite sides of the knee joint (see fig.2 reference object 14 is disposed opposite side of a knee joint 10); and a hinge system (see fig.2 reference object 10) having a flexion-extension regulating device (see fig.5 reference objects 42 and 44) engaged to the upper strut (see fig.2 reference object 12 is engaged to the hinge via reference objects 36,34 and 56), the device having an elongated main slot (see fig.5 reference objects 60) formed there through and providing a fixed boundary for prescribing a range of motion (see col.4 lines 1-14, 51-54); and a motion limiting member (see fig.5 reference object 68) engaged to the device (see fig.5, engaged via reference object 46) to the respective end portion of the lower strut (see fig.4 with end portion located near reference objects 40 and 38), the motion limiting member having a motion limiter (see fig.5 reference objects 70 and 72) disposed within the main slot which is caused to move there along (see col.4 lines 18-27) when the respective upper and lower struts pivot about the knee joint wherein confinement of the motion limiter within the fixed boundary ensures that the knee joint flexes and extends within the prescribed range of motion (see col.4 lines 18-31, col.14 lines 39-45).

14. **As to claim 17, Bledsoe discloses** the knee brace of claim 17 wherein the knee brace is a post-surgical knee brace (see col.1 lines 13-18).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4,9, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bledsoe US

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16. **As to claim 4, Bledsoe does not disclose** the hinge system of claim 1 wherein the upper and lower members are unitarily formed to each other. However, a close review of the specification suggests that the applicant does not establish criticality regarding the construction of the upper and lower members being unitarily formed to each other. Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to construct the upper and lower member as one unit or a separate unit because they are considered obvious design choice.

17. **As to claim 9, Bledsoe discloses** the hinge system of claim 1 wherein the prescribed range of motion is between about 0 to about 140 degrees (see col.8 lines 50-64). However, Bledsoe discloses that the hinge may be adjusted to permit movement through any limited range of motion (see col.4 lines 39-42). Therefore, Bledsoe's hinge is capable of providing 0-140 degrees of motion. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to adjust the limiting range of Bledsoe's hinge for the purposes of providing a patient with a desired range of motion including 0-140 degrees.

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18. **As to claim 19, Bledsoe discloses** the hinge system of claim 17 wherein the prescribed range of motion is between about 0 to about 140 degrees (see col.8 lines 50-64). However, Bledsoe discloses that the hinge may be adjusted to permit movement through any limited range of motion (see col.4 lines 39-42). Therefore, Bledsoe's hinge is capable of providing 0-140 degrees of motion. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to adjust the limiting range of Bledsoe's hinge for the purposes of providing a patient with a desired range of motion including 0-140 degrees.

Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bledsoe US Patent 4,463,751 in view of Young US Patent 5,997,493

19. **As to claim 13, Bledsoe does not disclose** the hinge system of claim 1 further comprising at least one stop member removably disposed within the elongated main slot for adjusting the prescribed range of motion.

20. **As to claim 13, Young teaches** a hinge with movement limitation for use in orthosis, orthopedic splints and braces employed at the knee with one hinge member having a limiting means, pusher (see fig.1 reference objects 1066 and 1068) which is selectively lockable in variable incremental positions by means of engaging teeth and a second hinge member having a projection which prevents relative movement of the hinge members in a given direction once the projection contacts the limiting means (see col.2 lines 60-65). Young additionally teaches the first member has two limiting means variably disposed and releasably secured (reading the limitation "removably disposed") (see col.3 line 52) on either side of the projection (see col.2 lines 66-67), where one controls extension and the other control flexion of the knee (see col.3 lines 45-47).

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21. **Therefore**, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the hinge mechanism of Bledsoe in view of Young to provide the hinge mechanism with stop members on either side of the projection/flange for the purposes of further limiting the flexion and extension of the knee when the flange contacts the stop members.

22. **As to claim 20, Bledsoe does not disclose** the hinge system of claim 17 further comprising at least one stop member removably disposed within the elongated main slot for adjusting the prescribed range of motion.

23. **As to claim 20, Young teaches** a hinge with movement limitation for use in orthosis, orthopedic splints and braces employed at the knee with one hinge member having a limiting mean, pusher (see fig.1 reference objects 1066 and 1068) which is selectively lockable in variable incremental positions by means of engaging teeth and a second hinge member having a projection which prevents relative movement of the hinge members in a given direction once the projection contacts the limiting means (see col.2 lines 60-65). Young additionally teaches the first member has two limiting means variably disposed and releasably secured (reading the limitation "removably disposed") (see col.3 line 52) on either side of the projection (see col.2 lines 66-67), where one controls extension and the other control flexion of the knee (see col.3 lines 45-47).

24. **Therefore**, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the hinge mechanism of Bledsoe in view of Young to provide the hinge mechanism with stop members on either side of the projection/flange for the purposes of further limiting the flexion and extension of the knee when the flange contacts the stop members.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bledsoe US Patent 4,463,751 in view of Lamb et al. US Patent 4,523,585

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25. As to claim 15, Bledsoe does not disclose the hinge system of claim 1 further comprising an elongated arm member sized and configured to be disposed between the end portions of the upper and lower struts.

26. As to claim 15, Lamb et al. teach a knee brace applied to a patient's knee subsequent a fracture of tibia or femur, or after operation on the knee (see col.1 lines 5-7) having a crossed connecting links (see fig.1 reference object 24) having spaced pivotal axes (see fig.1 reference objects 26' and 32') connected to a upper extension link (see fig.1 reference object 12) and a lower extension link (see fig.1 reference object 14) respectively (see col.3 lines 1-5) to allow peculiar motion desired for the knee movement (see col.3 line 13). Additionally, it would have been obvious to one of ordinary skills in the art that a connecting link (24) between two extension links/ struts is capable of holding the two struts in position.

27. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the hinge of Bledsoe in view of Lamb et al. in order to provide the hinge system with a cross connecting link/or elongated arm member for the purposes of allowing peculiar motion desired for the knee movement and holding the upper and lower struts in position.

Specification

28. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: As to claim 4, specification on page 13, lines 4-5, "the flexion-extension regulating device 24 is formed by attaching an upper member 26 and a lower member 28 together" does not provide proper antecedent basis to the claim limitation "unitarily formed to each other".

Claim Objections

29. Claim 10 is objected to because of the following informalities: since claim limitation "a first motion limiting surface" is not in the drawing, based on description provided on the limitations in the specification (page 14), examiner assumes that the applicant is referring to the back side of the second motion limiting surface (labeled as 54 in fig.3) as the first motion limiting surface. Appropriate correction is required.

30. Claim 16 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 16 limitations "elongated arm member is fabricated from metal" do not further limit the subject matter of its dependent claim 12. Therefore, claim 16 would not be examined. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Drawings

31. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference number 52 is not labeled in the associated figures 3-5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Allowable Subject Matter

32. Claims 14 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

33. The following is a statement of reasons for the indication of allowable subject matter: As to claims 14 and 21, the prior art of record does not teach nor render obvious the overall claimed combination of a stop member being fabricated from rubber. Additionally, the applicant has stated criticalities associated with the rubber fabrication: "...stop member made from semi-rigid rubber or plastic so that they can be frictionally retained within the inner slot periphery" (see specification page 19, 0045). Therefore, the invention defined in claim 14 and 21 is novel.

Conclusion

34. The prior art made of record on form PTO-892 and not relied upon shows various hinge system used in orthopedic devices.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

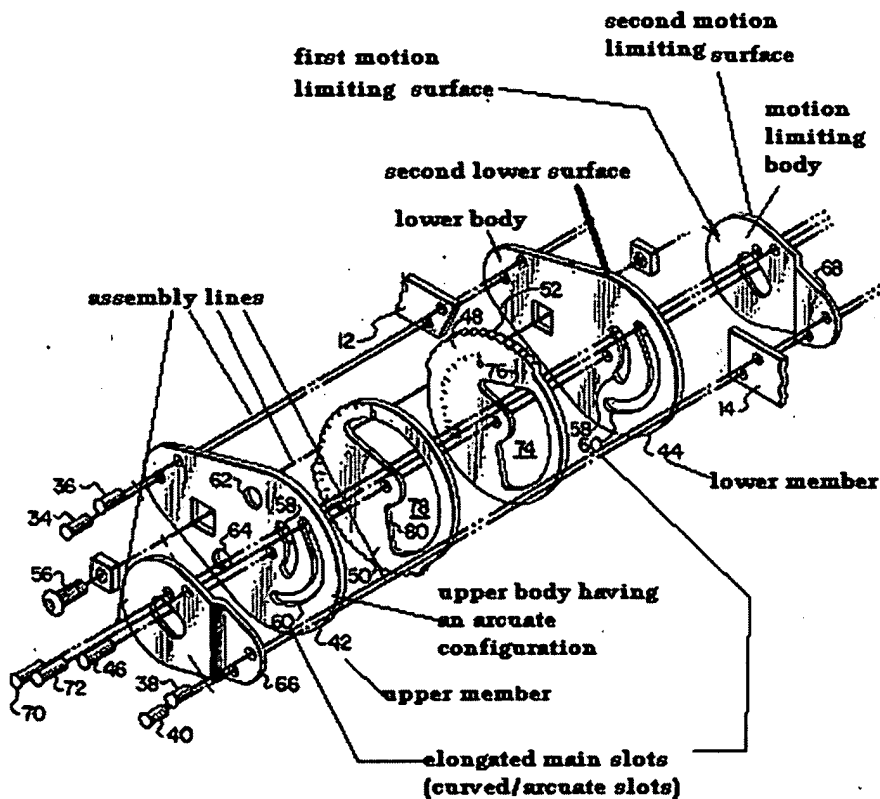
36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private

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PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

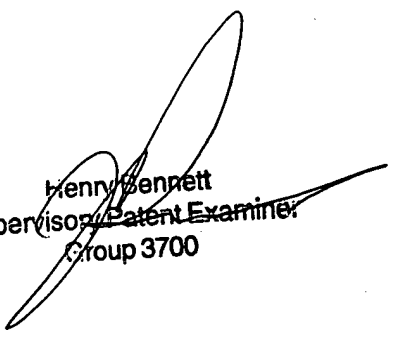
Shumaya Ali
 Shumaya B. Ali 3/4/2005
 Examiner
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**FIG. 5**

PRIOR ART
US PATENT 4,463,751
BLED SOE

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